EXHIBIT B

Expert opinion of Jaime L Sepulveda MD FACOG FACS PRPC
Gynemesh PS, Prolift and Prosima devices

I. Credentials and qualifications

My name is Jaime L. Sepulveda-Toro. My attached curriculum vitae reflects my education, training and unique qualifications to render opinions in this case. I graduated from the University of Puerto Rico with a Bachelor in Sciences in 1981 and from the University of Puerto Rico School of Medicine in 1985. I did a Postdoctoral Research Fellowship in Molecular Pharmacology at the same medical school followed by a direct internship and residency training program at the University of Puerto Rico University Hospital. Following completion of my residency program I had an appointment as assistant professor of Obstetrics and Gynecology at the University of Miami School of Medicine where I completed postgraduate education in Pelvic Surgery and Urogynecology. I have been in private practice since 1992.

I am Board Certified in Obstetrics and Gynecology with a subspecialty certification in Female Pelvic Medicine and Reconstructive Surgery. I also hold the only Pelvic Rehabilitation certification available to physicians and surgeons after becoming part of the first class of Certified Pelvic Rehabilitation Practitioners from Herman and Wallace Pelvic Rehabilitation Institute.

I am the Medical Director of the South Miami Medical Arts Surgery Center and Principal Investigator of the Fibroid Registry Research Project of the Center for Women and Infants at South Miami Hospital- Baptist Health, where I hold full privileges for gynecologic surgery. I am the Conference Director for the for the Pelvic Floor Board, a multi-specialty group of physicians specializing in colorectal surgery, physical medicine, urology, neurology, radiology, and urogynecology devoted to the discussion and analysis of challenging pelvic floor conditions seen at our hospital. I am a fellow of the American College of Obstetrics and Gynecology and also a Fellow of the American College of Surgeons. I am a member of the American Urogynecologic Society, the American Urological Association, the International Urogynecologic Association and the International Continence Society.

I have had extensive experience in the care of female urinary incontinence and pelvic organ prolapse. During my 23 years in practice I have seen the

evolution of continence and prolapse care with and without surgery. I have used native tissue repairs, sacral colpopexy, and the use of vaginal mesh (specifically polypropylene) for the treatment of pelvic organ prolapse. I have had experience in the treatment of complications arising from the use of native tissue, suture repairs, and synthetic and non-synthetic grafts for the surgical treatment of pelvic organ prolapse. My expertise extends to the daily use of diagnostic testing for urinary and fecal incontinence and pelvic organ prolapse.

I have used and continue using midurethral slings made of polypropylene in the care of my patients with urinary stress incontinence. I continue to use macroporous monofilament polypropylene in the transabdominal repair of pelvic organ prolapse and used Prolift and Prosima until decommercialized. I have accumulated experience with all three generations of midurethral slings, retropubic, transobturator and single incision.(TVT, TVTO and TVT Secur). I have also accumulated experience with the use of tension free Gynemesh PS, and the implantation of mesh for the treatment of moderate and severe prolapse with and without the use of trocars. I have also placed over 2,000 midureth eral slings, the vast majority of which use Prolene polypropylene. I have conducted various types of professional education activities for other surgeons on the use of Gynemesh PS, Prolift and Prosima. These activities encompassed implantation and use, the potential benefits and risks of the device, the IFU and professional education materials, as well as my clinical experience and the medical literature and studies.

I have devoted over a decade to study the anatomy of the obturator an area in which I have done surgery and have explored with the systematic study of its anatomy using imaging and cadaver dissections. I have studied the anatomy of this space through the dissection of over 300 cadaver specimens and through MRI imaging of cadaver and patients. I have had over 500 physicians visit my operating room and watch me place a transobturator sling, and in the use of Prolift and the use of Prosima. These visits have been with and without industry sponsorship. Over the years I have spoken to colleagues, scientist researchers, engineers and anatomists getting a thorough understanding of the mechanism safety, operative technique and management of intraoperative and postoperative complications of repairs with and without synthetic non absorbable mesh for the treatment of prolapse and incontinence.

I have researched and regularly read the medical and scientific literature concerning prolapse and its treatment, including the mechanism, efficacy and safety of abdominal and transvaginal mesh. Over the years I have spoken to colleagues, scientists, researchers, engineers and anatomists to get a thorough understanding of the mechanism, efficacy and safety of abdominal and transvaginal prolapse mesh repair. I have counseled my patients on the inherent risks of all prolapse procedures, including the risk of revision whenever a permanent suture or mesh graft is used.

My education and experience in clinical sciences has allowed me to discriminate the clinical relevance of all information involved in the placement and outcomes of prolapse mesh. My background in basic sciences, specifically my formal training in molecular pharmacology including benchwork preparation of cytotoxicity assays, gives me a unique expertise in implants science.

A list of materials that I have reviewed is attached and includes company documents, the medical literature, and materials relating to Gynemesh PS, Prolift, and Prosima. All of my opinions are held to a reasonable degree of medical and scientific certainty. I have also reviewed the reports of experts for the Plaintiffs. I reserve the right to amend this report and my opinions pending receipt of additional materials.

II. Overview and Review of literature

Pelvic organ prolapse, like urinary incontinence, is a common condition in women. There are various types of prolapse including cystocele, rectocele and vault prolapse with cystocele being the most common. A cross sectional analysis of the WHI revealed that in women with a uterus, the rate of uterine prolapse was 14.2%, the rate of cystocele was 34.3%, and the rate of rectocele was 18.6% and in the women who had undergone a hysterectomy, the prevalence of cystocele was 32.9% and rectocele was 18.3%.[1] The prevalence of prolapse increases with age and is a major public health concern as our population ages. The lifetime risk of surgery for POP in American women is 12.6% and the combined rate for either SUI or POP surgery is 20.0% per a

[1] Hendrix SL, Clark A, Nygaard I, Aragaki A, Barnabei V, McTiernan A. Pelvic organ prolapse in the Women's Health Initiative: gravity and gravidity. Am J Obstet Gynecol. 2002 Jun;186(6):1160-6.

study evaluating a large, population-based cohort of more than 10 million women.[2]

Risk factors include pregnancy, childbirth, congenital or acquired connective tissue abnormalities, denervation or weakness of the pelvic floor, aging, hysterectomy, menopause, and factors associated with chronically raised intra-abdominal pressure such as repetitive heavy lifting, smoking, chronic cough and COPD.[3] The pelvic floor support system gets its first test at the first vaginal delivery with lower levels of damage after subsequent deliveries. The damage of a vaginal delivery is permanent and is characterized by a torn fibromuscular support to the pelvic organs. With impaired support, the resistance to hold organs in place is lower than the force generated by an increase in intra-abdominal pressure and the transmitted pressure to the pelvic floor. Restoration of the deficient pelvic floor support structure by placing a durable prosthesis to support the pelvic organs forms the scientific rationale to treat pelvic organ prolapse with synthetic mesh.

Symptoms of pelvic organ prolapse include vaginal bulging, pelvic heaviness, urinary voiding problems and urinary incontinence, bowel changes, vaginal discharge, dyspareunia and sexual dysfunction, pelvic and lower abdominal pain, and are associated with poorer quality of life.[4] The burden of untreated prolapse is significant. Studies have shown that POP adversely affects numerous aspects of a woman's quality of life including social, psychological, physical, sexual, body image and overall wellbeing.[5]

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[2] Wu JM, Matthews CA, Conover MM, Pate V, Jonsson Funk M. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. Obstet Gynecol. 2014 Jun;123(6):1201-6.
[3] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev. 2016 Feb 9;2:CD012079. [Epub ahead of print]
[4] Fritel X, Varnoux N, Zins M, Breart G, Ringa V. Symptomatic pelvic organ prolapse at midlife, quality of life, and risk factors. Obstet Gynecol. 2009 Mar; 113(3):609-16.
[5] Rogers GR, Villarreal A, Kammerer-Doak D, Qualls C. Sexual function in women with and without urinary incontinence and/or pelvic organ prolapse. Int Urogynecol J. 2001;12:361–365; Ozel B, White T, Urwitz-Lane R, Minaglia S. The impact of pelvic organ prolapse on sexual function in women with urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2006 Jan;17(1):14-7; Handa VL, Cundiff G, Chang HH, Helzlsouer KJ. Female sexual function and pelvic floor disorders. Obstet Gynecol. 2008 May;111(5):1045-52; Ghetti C, Lowder JL, Ellison R, Krohn MA, Moalli P. Depressive symptoms in women seeking surgery for pelvic organ prolapse. Int Urogynecol J. 2010 Jul;21(7):855–60; Lowder J, Ghetti C, Moalli P, Zyczynski H, Cash TF. Body image in women before and after

Conservative options such as pelvic floor exercises and use of a pessary are often offered, but patient understanding and follow through lead many to choose a surgical option.

The use of native tissue surgical repair for prolapse has been associated with high rates of recurrence of 30 to 50%.[6] The high failure rates as well as complications led surgeons to use synthetic materials to augment the deficient pelvic floor support structure via the abdominal approach beginning over 50 years ago.[7] However, the preferred route for the majority of prolapse surgeries in the United States is vaginal (80-90%),[8] and there was a trend in the progressive movement towards less invasive vaginal hysterectomies, which are often performed concomitantly. Prolapse following hysterectomy is also common and often involves a combination of failures to the pelvic levels of support including a loss of apical support which is frequently seen with more advanced degrees of prolapse extending beyond the hymen.[9] These

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reconstructive surgery for pelvic organ prolapse. International Urogynecology Journal. 2010;21(8):919–925;

[6] Benson JT, Lucente V, McClellan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. Am J Obstet Gynecol. 1996;175:1418–21; Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol. 1997; 89(4):501–506; Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001; 185(6):1299–1304; Sand PK, Koduri S, Lobel RW, et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol. 2001;184(7):1357–1362; Clark AL, Gregory T, Smith VJ, Edwards R. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol. 2003;189(5):1261–1267; Whiteside JL, Weber AM, Meyn LA, Walters MD. Risk factors for prolapse recurrence after vaginal repair. Am J Obstet Gynecol. 2004;191(5):1533–1538.

[7] Lane FE. Repair of posthysterectomy vaginal-vault prolapse. Obstet Gynecol. 1962 Jul; 20:72-7.

[8] Brown JS, Waetjen LE, Subak LL, Thom DH, Van den Eeden S, Vittinghoff E. Pelvic organ prolapse surgery in the United States, 1997. Am J Obstet Gynecol. 2002; 186:712–16; Boyles SH, Weber AM, Meyn L. Procedures for pelvic organ prolapse in the United States, 1979-1997. Am J Obstet Gynecol. 2003; 188:108–15.

[9] DeLancey JO. Anatomic aspects of vaginal eversion after hysterectomy. Am J Obstet Gynecol 1992; 166:1717-28; Chen L, Ashton-Miller JA, Hsu Y, DeLancey JO. Interaction among apical support, levator ani impairment, and anterior vaginal wall prolapse. Obstet Gynecol. 2006;108:324–32; Rooney K, Kenton K, Mueller ER, FitzGerald MP, Brubaker L.

factors and the demonstrated benefit of mesh augmentation for pelvic organ prolapse via the abdominal route shown in a Level 1 randomized controlled trial[10] led to the use of transvaginal non-absorbable mesh utilization for pelvic organ prolapse which demonstrated efficacy and a known safety profile.[11] Absorbable mesh was studied early on in prolapse repair with mixed results.[12] The use of synthetic mesh for hernia repair had been utilized for over 60 years.[13] Moreover, the vaginal placement of synthetic slings for the treatment of stress urinary incontinence had also been described,[14] and the midurethral TVT macroporous polypropylene sling demonstrated that the vaginal

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Advanced anterior vaginal wall prolapse is highly correlated with apical prolapse. Am J Obstet Gynecol. 2006; 195:1837–40.

[10] Benson JT, Lucente V, McClellan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. Am J Obstet Gynecol. 1996; 175:1418–21.

[11] Julian TM. The efficacy of Marlex mesh in the repair of severe, recurrent vaginal prolapse of the anterior midvaginal wall. Am J Obstet Gynecol. 1996;175:1472–1475; Flood CG, Drutz HP, Waja L. Anterior colporrhaphy reinforced with Marlex mesh for the treatment of cystoceles. Int Urogynecol J Pelvic Floor Dysfunct. 1998;9:200–204; Nicita G. A new operation for genitourinary prolapse. J Urol. 1998;160:741–745; Hardiman P, Oyawoye S, Browning J. Cystocele repair using polypropylene mesh. Br J Obstet Gynaecol. 2000;107:825–826; Migliari R, De Angelis M, Madeddu G, Verdacchi T. Tension-free vaginal mesh repair for anterior vaginal wall prolapse. Eur Urol. 2000;38:151–155; De Tayrac R, Gervaise A, Fernandez H. [Cystocele repair by the vaginal route with a tension-free sub-bladder prosthesis] J Gynecol Obstet Biol Reprod (Paris) 2002;31:597–599; Adhoute F, Soyeur L, Pariente JL, Le Guillou M, Ferriere JM. [Use of transvaginal polypropylene mesh (Gynemesh) for the treatment of pelvic floor disorders in women. Prospective study in 52 patients] Prog Urol. 2004;14:192–196.

[12] Weber AM, Walters MD, Piedmonte MR, Ballard LA. Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol. 2001; 185(6):1299–1304; Sand PK, Koduri S, Lobel RW, et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol. 2001;184(7):1357–1362.

[13] Usher FC, Hill JR, Ochsner JL. Hernia repair with Marlex mesh. A comparison of techniques. Surgery. 1959 Oct;46:718-24; Luijendijk RW, Hop WC, van den Tol MP, de Lange DC, Braaksma MM, IJzermans JN, Boelhouwer RU, de Vries BC, Salu MK, Wereldsma JC, Bruijninckx CM, Jeekel J. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med. 2000 Aug 10;343(6):392-8.

[14] Moir JC. The gauze-hammock operation. (A modified Aldridge sling procedure). J Obstet Gynaecol Br Commonw. 1968 Jan; 75(1):1-9; Morgan JE. A sling operation, using Marlex polypropylene mesh, for treatment of recurrent stress incontinence. Am J Obstet Gynecol. 1970 Feb 1; 106(3):369-77.

approach was feasible.[15] The monofilament macroporous Prolene PP also demonstrated useful attributes, tolerability and had a long history of use as both a mesh and a suture.[16]

Gynemesh PS was cleared by the FDA on January 8, 2002 for use in pelvic organ prolapse. Gynemesh PS is a macroporous type 1 monofilament polypropylene mesh with a pore size of 2.4mm and a light weight of 42 g/m^2 for the prolapse indication. It was studied in a one year study and demonstrated efficacy and safety.[17] In 2002, a group of French surgeons began studying and developing a standardized way, mesh and device to treat prolapse.[18] Vypro mesh was assessed and was not tolerated.[19]

The TVM Group settled on Gynemesh PS which was state of the art and biocompatible. After several years of study by the TVM Group[20] and including

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[15] Rezapour M, Falconer C, Ulmsten U. Tension-Free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)--a long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S12-14; Rezapour M, Ulmsten U. Tension-Free vaginal tape (TVT) in women with recurrent stress urinary incontinence--a long-term follow up. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S9-11; Rezapour M, Ulmsten U. Tension-Free vaginal tape (TVT) in women with mixed urinary incontinence--a long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12 Suppl 2:S15-18; Ward K, Hilton P on behalf of the UK and Ireland TVT Trial Group. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. BMJ 2002; 325:67.

[16] Falconer C, et al. Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. Int Urogynecol J Pelvic Floor Dysfunct. 2001; 12 Suppl 2:S19-23; Petros P. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond: Ulf Ulmsten Memorial Lecture 2014. Int Urogynecol J. 2015 Apr; 26(4):471-6.

[17] Lucente V, Hale D, Miller D, Madigan J. A Clinical Assessment of GYNEMESH PS for the Repair of Pelvic Organ Prolapse (POP). J Pelvic Med Surg 2004; 10:Supp.1 Oral Poster 55.

[18] Debodinance P, Berrocal J, Clavé H, Cosson M, Garbin O, Jacquetin B, Rosenthal C, Salet-Lizée D, Villet R. [Changing attitudes on the surgical treatment of urogenital prolapse: birth of the tension-free vaginal mesh]. J Gynecol Obstet Biol Reprod (Paris). 2004 Nov;33(7):577-88.

[19] Denis S, Bernard J, Joël A, Lemli O. Pelvic organ prolapse treatment by the vaginal route using a Vypro® composite mesh: preliminary results about 106 cases. ICS IUGA 2004 Abs 620. http://www.ics.org/Abstracts/Publish/42/000620.pdf

[20] Cosson M, Caquant F, Collinet P, Rosenthal C, Clave H, Debodinance P, Garbin O, Berrocal J, Villet R, Jacquetin B. Prolift mesh (Gynecare) for pelvic organ prolapse surgical treatment using the TVM group technique: a retrospective study of 687 patients. ICS 2005 Abs 121. http://www.ics.org/Abstracts/Publish/43/000121.pdf

the one year Gynemesh PS study earlier mentioned, all together totaling over 700 patients, the Prolift was introduced in 2005. Prospective multi center TVM studies using Gynemesh PS were started in 2004 and would report data beginning in 2005 at 6 months, with later presentations at 1, 3 and 5 years.[21] This is a significant amount of study and well surpassed all industry standards at the time for prolapse mesh.

By 2009 more than 30 studies were reported in the literature comprising over 4,000 patients. Since that time, Gynemesh PS and Prolift have continued to be studied, more so than any other mesh for the treatment of prolapse. These data document the favorable benefit to risk profile.

Gynemesh PS and Prolift have been studied in several randomized controlled trials which overall demonstrate anatomic superiority to native tissue, statistically significant subjective and quality of life improvements, and lower rates of reoperation.[22]

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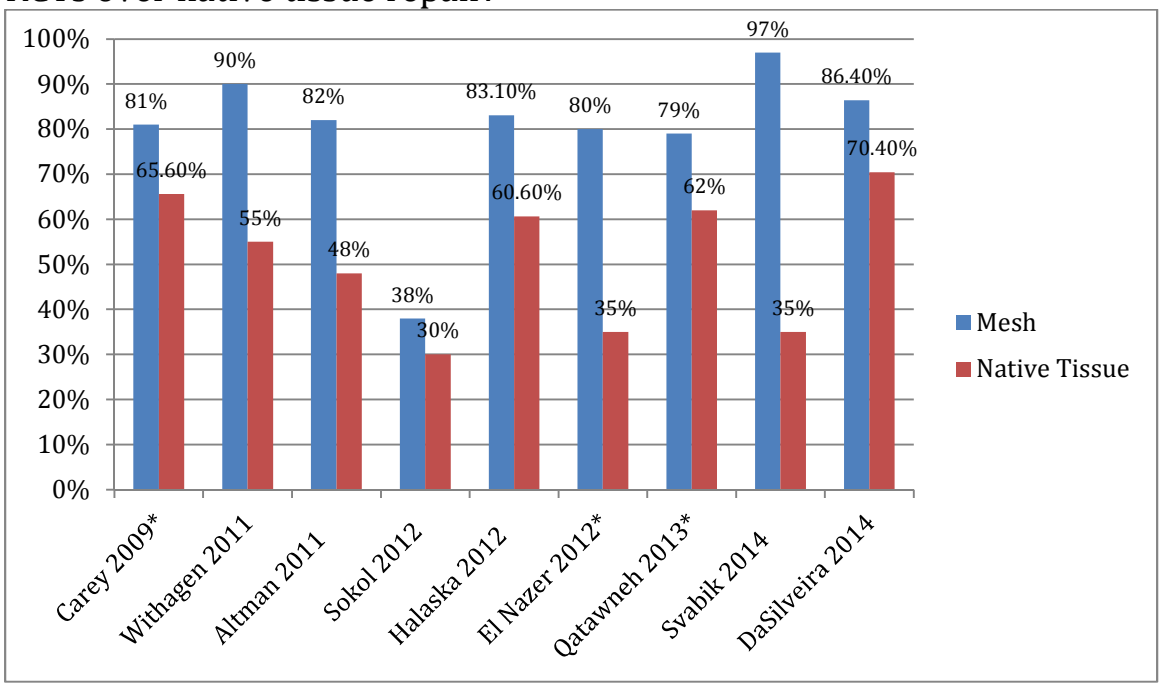
[21] Jacquetin B, Fatton B, Rosenthal C, Clavé H, Debodinance P, Hinoul P, Gauld J, Garbin O, Berrocal J, Villet R, Salet Lizée D, Cosson M. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 3-year prospective follow-up study. Int Urogynecol J. 2010 Dec;21(12):1455-62; Miller D, Lucente V, Babin E, Beach P, Jones P, Robinson D. Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results. Female Pelvic Med Reconstr Surg. 2011 May;17(3):139-43; Jacquetin B, Hinoul P, Gauld J, Fatton B, Rosenthal C, Clavé H, Garbin O, Berrocal J, Villet R, Salet-Lizée D, Debodinance P, Cosson M. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J. 2013 Oct;24(10):1679-86.

[22] Carey M, Higgs P, Goh J, Lim J, Leong A, Krause H, Cornish A. Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG. 2009 Sep;116(10):1380-6; Withagen MI, Milani AL, den Boon J, Vervest HA, Vierhout ME. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol. 2011 Feb;117(2 Pt 1):242-50; Altman D, Väyrynen T, Engh ME, Axelsen S, Falconer C; Nordic Transvaginal Mesh Group. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med. 2011 May 12;364(19):1826-36. doi: 10.1056/NEJMoa1009521. Erratum in: N Engl J Med. 2013 Jan 24;368(4):394; Sokol AI, Iglesia CB, Kudish BI, Gutman RE, Shveiky D, Bercik R, Sokol ER. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. Am J Obstet Gynecol. 2012 Jan;206(1):86.e1-9; Halaska M, Maxova K, Sottner O, Svabik K, Mlcoch M, Kolarik D, Mala I, Krofta L, Halaska MJ. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. Am J Obstet Gynecol. 2012 Oct;207(4):301.e1-7; El-Nazer MA, Gomaa IA, Ismail Madkour WA, Swidan KH, El-Etriby MA. Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a

The chart below shows the anatomic superiority of Gynemesh PS* and Prolift RCTs over native tissue repair.



These studies also show positive effects on numerous domains including high patient satisfaction, improvement in bowel, prolapse and sexual function and show a positive benefit to risk profile. In the largest RCT by Altman 2011, 75.4% of anterior Prolift patients had no symptoms of vaginal bulge compared to 62% for the anterior colporrhaphy group (p=0.008). In the El-Nazer 2012 Gynemesh PS RCT, subjective symptom improvements in urinary incontinence or urgency, voiding difficulty, vaginal pressure/bulge and sexual dysfunction symptoms were seen in the Gynemesh PS arm and voiding difficulty and vaginal bulge symptoms were significantly improved with

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comparative clinical study. Arch Gynecol Obstet. 2012 Oct;286(4):965-72; Qatawneh A, Al-Kazaleh F, Saleh S, Thekrallah F, Bata M, Sumreen I, Al-Mustafa M. Transvaginal cystocele repair using tension-free polypropylene mesh at the time of sacrospinous colpopexy for advanced uterovaginal prolapse: a prospective randomised study. Gynecol Surg 2013; 10:79–85; Svabik K, Martan A, Masata J, El-Haddad R, Hubka P. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. Ultrasound Obstet Gynecol. 2014 Apr;43(4):365-71; Dos Reis Brandão da Silveira S, Haddad JM, de Jármy-Di Bella ZI, Nastri F, Kawabata MG, da Silva Carramão S, Rodrigues CA, Baracat EC, Auge AP. Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. Int Urogynecol J. 2015 Mar;26(3):335-42.

Gynemesh PS compared to native tissue repair ($p<0.05$). Besides significantly better anatomic cure, the da Silveira 2014 RCT reported statistically significant higher patient quality of life improvements with Total Prolift versus native tissue SSL repair. The Carey 2009 Gynemesh PS RCT reported 91.5% satisfaction with surgery and symptoms and quality-of-life improvements data were observed with Gynemesh PS.

In the Withagen 2011 Prolift RCT, Defecatory Distress Inventory domains of "pain" and "incontinence" scored significantly better in the Prolift group compared to native tissue at 12 months ($p=0.01$ and $p=0.05$). Additionally, significant improvements in the Urogenital Distress Inventory domains "genital prolapse," "pain" and "overactive bladder," and "physical functioning" of the Incontinence Impact Questionnaire were noted. In the Sokol 2012 Prolift RCT, quality of life improved and 96.2% of patients reported a cure of bulge symptoms. In the Halaska 2012 Prolift RCT, significant improvements were reported based on Urinary, Colorectoanal and Pelvic Organ Prolapse Impact Questionnaires. Prolift also had higher improvement in bowel symptoms than the SSL arm.

The most recent Cochrane Review demonstrates that there are lower rates of awareness of prolapse, reoperation for prolapse, and prolapse on examination with permanent polypropylene mesh like Gynemesh PS compared to native tissue repair and there is no difference in repeat surgery for incontinence or dyspareunia versus native tissue repair.[23] Although Ultrapro and PVDF have been referenced by some of the Plaintiffs' experts as a safer alternative than Gynemesh PS, the data including the Cochrane Review do not support this as there is still a risk of mesh exposure of 15% and a 9% rate of dyspareunia with Ultrapro in the Prolift +M device. The data also do not demonstrate that Ultrapro mesh is more effective than Gynemesh PS.

Similar to the Cochrane Review's findings regarding permanent polypropylene mesh, the above-referenced Gynemesh PS and Prolift studies demonstrate an overall positive effect on sexual function with many patients having dyspareunia at baseline resolve after surgery. These data also do not show a statistically significant difference in de novo dyspareunia, de novo

[23] Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Marjoribanks J. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database Syst Rev. 2016 Feb 9;2:CD012079. [Epub ahead of print] Review. PubMed PMID: 26858090.

pelvic pain or vaginal pain, change in sexual function, or change in vaginal length or vaginal caliber. This is consistent with the findings by Dietz and Maher whose systematic review found no difference in post-operative or de novo dyspareunia or change in sexual function as assessed by PISQ for mesh versus native tissue repair.[24]

Significant dyspareunia and sexual dysfunction rates at baseline are demonstrated in these and other studies. It has long been known that dyspareunia is common in women with pelvic floor disorders. It has also long been known that prolapse repair can lead to dyspareunia.[25] The rates seen with Gynemesh PS and Prolift are generally lower than or equivalent to native tissue repair as seen in the study by Lowman below.[26]

TABLE 4
De novo dyspareunia after prolapse surgery

Dyspareunia	ASC N = 224 (148)[a] Handa et al[21]	SSLF N = 287 (106)[a] Maher et al[6]	USS N = 110 (34)[a] Silva et al[27]	APR N = 165 (81)[a] Weber et al[18]	Prolift N = 129 (57)[a]
Baseline (preop) dyspareunia (%)	40.5 (60/148)	Unknown	20.6 (7/34)	8.0 (6/81)	36.8 (21/57)
De novo (postop) dyspareunia (%)	14.5 (11/76)	36.1 (22/61)	25.9 (7/27)	19.0 (14/75)	16.7 (6/36)

[a] Number sexually active preop.

Lowman. Does the Prolift system cause dyspareunia? Am J Obstet Gynecol 2008.

Vaginal wound dehiscence, graft and biologic erosion, and wound complications can occur with any prolapse repair. They are multifactorial and not infrequently seen by vaginal surgeons even when using native tissue repair. Suture erosions and granulation tissue are seen in 15-40% of patients in numerous studies. A 36% suture-related complication rate at 18.9 months follow up including a 25% rate of suture removal with SSL native tissue repair has been reported.[27] A study of USLS found a 44% suture related

[24] Dietz V, Maher C. Pelvic organ prolapse and sexual function. Int Urogynecol J. 2013 Nov;24(11):1853-7.
[25] Francis WJ, Jeffcoate TN. Dyspareunia following vaginal operations. J Obstet Gynaecol Br Commonw. 1961 Feb;68:1-10.
[26] Lowman JK, Jones LA, Woodman PJ, Hale DS. Does the Prolift system cause dyspareunia? Am J Obstet Gynecol. 2008 Dec;199(6):707.e1-6.
[27] Toglia MR, Fagan MJ. Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture. Am J Obstet Gynecol. 2008 May;198(5):600.e1-4.

complication rate including 36% rate of suture erosion.[28] In the Sokol 2012 Prolift RCT, there was a 15% rate of mesh exposure and a 15% rate of suture erosion in the native tissue group. In the Svabik 2014 Prolift RCT there was a 8% mesh exposure rate and a 15% granulation tissue rate in the SSLF group.

In the recent multicenter NIH sponsored OPTIMAL RCT which compared USLS to SSL native tissue repairs, 19% and 14% rates of granulation tissue and 15% and 17% suture erosion rates were reported for USLS and SSL respectively at 6-24 months follow up.[29] A systematic review by the Society of Gynecologic Surgeons comparing synthetic and biologic grafts for prolapse reported a 10.3% erosion rate (synthetic 10.3%; biological 10.1%) and a 7.8% wound granulation rate (synthetic 6.8%; biological 9.1 %).[30]

Mesh exposure is the only unique complication with Gynemesh PS and Prolift although as noted above other wound complications occur without the use of mesh.[31] In many cases it can be treated conservatively with estrogen or a simple office procedure to excise the exposure. The vagina wound opens at the site of least resistance, the incision line, under a variety of stressors. Although infection has been theorized to be a factor due to the convention of a "clean contaminated environment," the evidence does not support that the separation of the incision edges in the vagina is primarily due to infection as infection rates do not correlate with mesh exposure rates with Gynemesh PS,

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[28] Yazdany T, Yip S, Bhatia NN, Nguyen JN. Suture complications in a teaching institution among patients undergoing uterosacral ligament suspension with permanent braided suture. Int Urogynecol J. 2010 Jul;21(7):813-8.

[29] Barber MD, Brubaker L, Burgio KL, Richter HE, Nygaard I, Weidner AC, Menefee SA, Lukacz ES, Norton P, Schaffer J, Nguyen JN, Borello-France D, Goode PS, Jakus-Waldman S, Spino C, Warren LK, Gantz MG, Meikle SF; Eunice Kennedy Shriver National Institute of Child Health and Human Development Pelvic Floor Disorders Network. Comparison of 2 transvaginal surgical approaches and perioperative behavioral therapy for apical vaginal prolapse: the OPTIMAL randomized trial. JAMA. 2014 Mar 12;311(10):1023-34 (Suppl. App.).

[30] Abed H, Rahn DD, Lowenstein L, Balk EM, Clemons JL, Rogers RG; Systematic Review Group of the Society of Gynecologic Surgeons. Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J. 2011 Jul;22(7):789-98.

[31] Murphy M, Holzberg A, van Raalte H, Kohli N, Goldman HB, Lucente V; Pelvic Surgeons Network. Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse". Int Urogynecol J. 2012 Jan;23(1):5-9.

which is a macroporous, monofilament polypropylene mesh. The overall data do not show a statistically significant increased risk of infection and the larger studies report infection rates that are lower than alternative surgeries. For example, de Landsheere reported a rate of 0.2% for surgery to treat mesh infection in a large cohort of 524 Prolift patients with 38 months follow up.[32] In addition, there was a low rate of 0.4% for surgery due to symptomatic contraction, a 2.5% rate of surgery to treat mesh exposure, and a 3% rate of reoperation for prolapse recurrence in this cohort. Another longer term study with 54 months follow up reported an 85% cure rate, no reoperations for recurrence, a 5.3% mesh exposure rate of which two were excised and two resolved with estrogen, and no infections.[33]

Bacteriological analysis of explants have shown flawed collection methodology, lack of prospective design and lacked an explant of Prolene polypropylene specimen.[34] Additionally, the presence of bacteria at the surgical site is not equivalent to infection.[35]

Other factors contributing to exposure or wound complications in native tissue repair include the formation of a hematoma at dissection sites. As a hematoma of significant volume is accumulated under the vaginal epithelium, the volume creates enough pressure to find a course and drain though the incision. The incision is being held by absorbable sutures and progressive loss of tensile strength is expected from the moment the sutures are placed. Once the incision is open the exposure of the implant is evident. The limited dissection required for implantation of these devices decreases the potential risk of wound dehiscence. The role of mechanical disruption of the wound at the suture line, smoking, and deleterious effect of a catheter in the wound healing process are important factors to consider in the etiology of exposure.

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[32] de Landsheere L, Ismail S, Lucot JP, Deken V, Foidart JM, Cosson M. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan;206(1):83.e1-7.

[33] Benbouzid S, Cornu JN, Benchikh A, Chanu T, Haab F, Delmas V. Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up. Int J Urol. 2012 Nov;19(11):1010-6.

[34] Boulanger L, Boukerrou M, Rubod C, Collinet P, Fruchard A, Courcol RJ, Cosson M. Bacteriological analysis of meshes removed for complications after surgical management of urinary incontinence or pelvic organ prolapse. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Jun; 19(6):827-31.

[35] Culligan P, Heit M, Blackwell L, Murphy M, Graham CA, Snyder J. Bacterial colony counts during vaginal surgery. Infect Dis Obstet Gynecol. 2003; 11(3):161-5..

Overall, these data show that the Gynemesh PS and Prolift are safe and effective. Efficacy and cure is high and better than native tissue repair. There are high levels of patient satisfaction and improvements in distressing symptoms and quality of life which shows the utility of the devices. There are no differences in pelvic pain, vaginal pain, dyspareunia or change in vaginal length or caliber and no significant difference in change in sexual function compared to native tissue prolapse repair.

I have also used the Prosima device, which is a trocarless system that utilized Gynemesh PS and a Vaginal Support Device (VSD) for moderate symptomatic pelvic organ prolapse. Like Prolift, it underwent many years of study with development and testing of surgical technique, prototype and mesh configuration. Study began in 2004 and the device was not introduced until more than five years later. Over time the device and technique were honed to provide a safe and effective method.[36]

The 12 and 29 month Prosima study results demonstrate good efficacy and a positive safety profile.[37] Anatomic cure is a little less than that seen with Prolift, although there is a high degree of lack of awareness of vaginal bulge and patient satisfaction which corresponds with the rates of 87% and 84.5% of patients with prolapse above the hymen at these time intervals. Overall there are low rates of dyspareunia and a positive effect on preexisting dyspareunia and sexual function. The cumulative mesh exposure rate for this

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[36] Carey M, Slack M, Higgs P, Wynn-Williams M, Cornish A. Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device. BJOG. 2008 Feb;115(3):391-7; Zyczynski HM, Carey MP, Smith AR, Gauld JM, Robinson D, Sikirica V, Reisenauer C, Slack M; Prosima Study Investigators. One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol. 2010 Dec;203(6):587.e1-8; Reisenauer C, Shiozawa T, Huebner M, Slack M, Carey MP. Anatomic study of prolapse surgery with nonanchored mesh and a vaginal support device. Am J Obstet Gynecol. 2010 Dec;203(6):590.e1-7.

[37] Zyczynski HM, Carey MP, Smith AR, Gauld JM, Robinson D, Sikirica V, Reisenauer C, Slack M; Prosima Study Investigators. One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol. 2010 Dec;203(6):587.e1-8; Sayer T, Lim J, Gauld JM, Hinoul P, Jones P, Franco N, Van Drie D, Slack M; Prosima Study Investigators. Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and vaginal support device. Int Urogynecol J. 2012 Apr;23(4):487-93.

extended follow-up period was 9.1%, with only one report of mesh exposure beyond 1 year, which resolved following treatment with topical estrogen.

There have been several other studies of Prosima which demonstrate its efficacy and safety. Rates of objective/anatomic cure are reported generally in the 80-95% range with accompanying significant improvements in subjective measures, symptoms and quality of life, a low reoperation rate, a low rate of de novo dyspareunia with a positive effect seen on sexual function and resolution of pre-existing dyspareunia, and acceptable rates of mesh exposure in the range of 2-15% which can be treated in many cases with estrogen or excision.[38] Overall, like Gynemesh PS and Prolift, the Prosima device is safe and effective, useful in treating moderate prolapse, and is not defective in my opinion.

In 2008, the FDA published a Public Health Notice concerning surgical pelvic mesh. This Public Health Notice discussed both potential complications and counseling of patients. Pelvic floor surgeons using mesh to treat SUI and POP, would be aware of and would be expected to know of the Notice, the potential complications, as well as their severity and need for reoperation discussed

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[38] D'Afiero A, Tommaselli GA, Basilica F, Affinito P, Stanco D, Nappi C. Short term efficacy and safety of a single incision mesh (Prosima) for the treatment of pelvic organ prolapse. Int Urogynecol J 2011; 22 (Suppl 1):S1144-45 Pres 150; Khandwala S, Slack M, Hinoul P, Urquhart C, Al-Salihi S, A trocar-free procedure for vaginal prolapse repair using mesh and a vaginal support device - an observational registry. FPMRS 2011; 17:5(Supp 2)S164 Poster 143; Krofta L, Krcmar M, Otcenasek M, Feyereisl J, Kasikova E, Dlouha K. Pelvic organ prolpase surgery with non-anchored mesh implants and vaginal support device in women with moderate symptomatic prolapse: prospective study. Int Urogynecol J 2011; 22(Suppl 1):S115=16 IUGA Pres 116; Malinowski A, Maciolek-Blewniewska G, Wojciechowski M. Initial experience with Gynecare Prosima pelvic floor repair system. Int Urogynecol J 2011; 22 (Suppl 3):S1794-95 IUGA Pres 472; Singh R, Lim J, Muscat K, Carey M. Anatomic, functional and ultrasound outcomes after vaginal prolapse surgery using non-anchored mesh. ICS 2011 Abs 575; Chen J, Zhu L, Lang JH, Shi HH, Lou WJ, Sun ZJ, Gong XM. Prospective study on total pelvic reconstruction surgery with Prosima in the treatment of pelvic organ prolapse stage III. Chin J Obstet Gyn 2012; 47:664-8; DAfiero A, Tommaselli GA, Forleo F, Affinito P, Stanco D. Short-term effects of mesh augmented surgery for pelvic organ prolapse on functional outcomes and qol: a comparison between trocar guided and single incision devices. Int J Gynecol Obstet 2012; 19S3 Abs 0156; Bezhenar V & Guseva E. The pelvic floor repair with the use of Prosima implant – the assessment of complications and life quality. ICS 2013 Abs 765; Tsai CP, Hung MJ, Shen PS, Chen GD, Su TH, Chou MM. Factors that affect early recurrence after prolapse repair by a nonanchored vaginal mesh procedure. Taiwan J Obstet Gynecol. 2014 Sep;53(3):337-42.

therein, and recommendations made. In 2011 the FDA published an updated notice concerning POP meshes. This notice identified similar risks as earlier and a reported new risk, contraction. Notably, contraction was identified as a potential adverse event in the initial 2002 Gynemesh PS IFU, the initial 2005 Prolift IFU and the initial 2008 Prosima IFU and this well known risk which can lead to pain was also identified in Ethicon professional education which the IFUs also recommended surgeons undergo.

As noted, each Gynemesh PS, Prolift and Prosima device is accompanied by an IFU. I have reviewed these IFUs and find them adequate and complete for its use in the operating room by the intended users. As a surgeon, I understand that the IFU is not a comprehensive guide for the surgical treatment of POP. The IFU builds on the knowledge that we as pelvic floor surgeons have acquired through prior education, instruction and experience and warns that users should be pelvic floor surgeons familiar with surgical procedures and techniques regarding pelvic floor repair and nonabsorbable meshes before using the device. Moreover, the IFUs on the very first page state that training is recommended and available. The IFU adequately informs surgeons of the use of Gynemesh PS, Prolift, Prosima and the potential risks and complications.

For example, the initial 2005 Prolift IFU states that "Training on the use of the Gynecare Prolift Pelvic Floor Repair Systems is recommended and available. Contact your company sales representative to arrange for this training. Refer to the recommended surgical technique for the Gynecare Prolift Pelvic Floor Repair Systems for further information on the Gynecare Prolift procedures."

Ethicon's IFU warns pelvic floor surgeons:

WARNINGS AND PRECAUTIONS

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively the patient should be advised to refrain from intercourse, heavy lifting and/or exercise (e.g. cycling, jogging) until the physician determines when it is suitable for the patient to return to her normal activities.

- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.
- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

The pertinent adverse reactions are also set forth:
ADVERSE REACTIONS

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.

Additionally, the Prolift Surgeon's Resource Monograph, which Ethicon made available to surgeons in early 2007 provided detailed information on the following post-operative complications:

- Postoperative complications:
  - Hemorrhage
  - Hematoma
  - Fistula
  - Infection
  - Urinary Retention
  - Mesh Exposure
  - Mesh Erosion
  - Dyspareunia
  - Vaginal Pain

Similarly, Ethicon presented clinical data on Prolift in the Monograph regarding mesh exposure rates, de novo dyspareunia rates, and other complications.

The complications such as tissue contraction, scarring, pelvic pain and dyspareunia are well-known complications that can occur with any pelvic floor surgery, including Prolift. The complication of mesh erosion or exposure is a wound complication like those seen with non-synthetic mesh repair and is not caused by a defect in the mesh. These are well-known complications that surgeons learn in medical school, residency, fellowship, through continued medical education, peer-reviewed literature, discussions with colleagues, and the FDA Public Health Notifications.

I have conducted numerous activities for the purpose of professional education including surgical anatomy laboratories with the use of models and cadavers, consensus conferences among experienced users, surgical demonstrations in the operating room and didactic lectures. All these activities offer the opportunity to address the complications and details of the surgery along with the interpretation of the IFU. The professional education activities provided the opportunity to exchange knowledge among surgeons. Ethicon's professional education, which is recommended in the IFU, supplements the IFU.

I have used the Prolift and Prosima patient brochures in my practice. Both allow a patient to construct a base to be used in the conversation about the procedure. These brochures are not meant to supplant the informed consent process, but rather are a resource for additional information and mention complications inherent to continence procedures. The IFU, surgical technique guide, surgeons resource monograph, patient brochure, professional education, medical literature, the 2008 and 2011 FDA Public Health Notifications discuss potential complications to be addressed in the informed consent process and were available to surgeons.

There have been several claims made by the Plaintiff's experts regarding the Prolene polypropylene mesh and the devices which in my opinion are incorrect and lack scientific support. Moreover, the large volume of clinical data on Gynemesh PS (as well as the TVT slings) including the highest level of evidence and long term data are inconsistent with these theories.

The monofilament knitted Gynemesh PS polypropylene mesh has pores which are macroporous (over 75 microns). A pore size above 75 microns allows for the migration of neutrophils (9-12 microns) and mature inflammatory cells

(20 microns), considering that most studies are on explants. The clinical data show that the pore size, weight, and construct of Gynemesh PS polypropylene mesh is optimal for treating prolapse.

Explants from humans get forces well beyond the intended force for a sling or prolapse procedure; explants are in essence useless in the evaluation of the host-graft interaction. Explanted material is the subject of mechanical stressors beyond its limits and has no clinical predictive value.

The use of Prolene polypropylene has been used in millions of sutures, slings and Gynemesh PS. A Medline search for sarcoma and polypropylene does not yield a single case of sarcoma or malignancy due to the use of polypropylene material in humans. MSDS and rat studies reporting sarcoma formation after implantation of polypropylene discs and powder are not transferable to humans.[39] Raw materials as referenced in MSDS are not implanted in humans. Instead they are processed and formulated. The same is true for pharmaceuticals. The available data does not show any causal link between polypropylene and cancer.[40],[41],[42],[43]

There is no evidence of human cytotoxicity. Cytotoxicity assessment of the Ulmsten Prolene polypropylene sling using the ISO Elution method showed cell lysis and toxicity; however, this was not confirmed by the ISO Agarose Diffusion method.[44,45] Cytotoxicity assessment of normal production Prolene polypropylene using the Agarose Overlay Method and Extraction Filter

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[39] King AB, Goldman HB. Current controversies regarding oncologic risk associated with polypropylene midurethral slings. Curr Urol Rep. 2014 Nov;15(11):453. doi: 10.1007/s11934-014-0453-y. PubMed PMID: 25234187.
[40] Moalli P, Brown B, Reitman M, Nager C. Polypropylene mesh: evidence for lack of carcinogenicity. Int Urogynecol J. 2014 May;25(5):573-6.
[41] March 12, 2014 AUGS-SUFU Frequently Asked Questions by Providers: Mid-urethral slings for Stress Urinary Incontinence.
http://www.augs.org/p/bl/et/blogid=16&blogaid=194
[42] King AB, Zampini A, Vasavada S, Moore C, Rackley RR, Goldman HB. Is there an association between polypropylene midurethral slings and malignancy? Urology. 2014 Oct;84(4):789-92.
[43] Linder BJ, Trabuco EC, Carranza DA, Gebhart JB, Klingele CJ, Occhino JA. Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence. Int Urogynecol J. 2016 Feb 10. [Epub ahead of print] PubMed PMID: 26864666.
[44] ETH.MESH.08476311
[45] ETH.MESH.08476314

Method showed no cytotoxicity.[46,47] An exploratory cytotoxicity assessment of unwashed non-sterile Prolene polypropylene mesh raw material using the ISO Elution method did not show cytotoxicity or cell lysis.[48,49] Normal production Prolene polypropylene has not shown cytotoxicity at drug elution, ISO Agarose overlay method, or with the extraction /filter paper method. All testing methods use a monolayer of L-929 mouse fibroblast cells.[50,51]

Polypropylene is a stable and well-accepted biomaterial with a history of over five decades of use in mesh implants.[52] In recent years, concerns regarding implanted polypropylene degradation have been raised as a result of very high magnification images that show portions of some explanted synthetic meshes with "cracked" surfaces.[53] These case reports and case series of explants lack reliability and one cannot drawn any causal inference from them or extrapolate their reported SEM findings to the larger population. In the referenced Clave study there were several methodologic flaws. Moreover, only a minority of the explants were reported to have surface cracking and degradation and oxidation were not shown on chemical analyses. While the purported surface changes were hypothesized to lead to adverse clinical outcomes, these hypotheses have not been confirmed. Nor are these hypotheses supported by the extensive peer-reviewed literature.

The medical literature including over 100 Gynemesh PS studies, meta-analyses and systematic reviews do not support that the mesh is cytotoxic, that it degrades or leads to a harmful inflammatory response in humans. To the contrary, the use of macroporous Type 1 Prolene polypropylene is the most biocompatible material for use to treat pelvic organ prolapse as evidenced by the high level data. The high degree of efficacy, the low rates of complications, the lack of a significant increased risk of dyspareunia or sexual function as compared to non-mesh native tissue repair, and the low rates of reoperation based on the highest level of scientific data are inconsistent with

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[46] ETH.MESH.08476315
[47] ETH.MESH.08476316
[48] ETH.MESH.08476317
[49] ETH.MESH.08476318
[50] ETH.MESH.08476315
[51] ETH.MESH.08476316
[52] AUGS-SUFU FAQs by Providers on Mid-urethral Slings for SUI, 2014.
[53] Clavé A, Yahi H, Hammou JC, Montanari S, Gounon P, Clavé H. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. Int Urogynecol J. 2010 Mar;21(3):261-70.

and refute the Plaintiff's experts' claims and hypotheses, which in essence are speculation and conjecture based on irrelevant, unreliable and/or low level data.

Overall the data show that Gynemesh PS, Prolift and Prosima are safe and effective. They are not defective and instead these well studied devices have significant usefulness and utility. In my opinion the data does not support the theories that the mesh is cytotoxic, that it degrades or causes a harmful inflammatory response, that the pore size, weight, or other features are harmful or cause significant clinical outcomes.

I reserve the right to supplement or modify my expert opinion based on the discovery, disclosure and timely provision of new findings and the depositions of the Plaintiffs' experts.

III. Fees & Testimony

My hourly charge is $500.00 per hour.

In the past four years, I have given testimony as an expert in the following cases: Cavness v. Johnson & Johnson, et al., (9/30/2015 trial testimony) and Sandra Garcia v. Johnson & Johnson, Cameron County, TX Case No. 2013-DCL-3511-D (3/13/2015 deposition testimony).

Jaime L. Sepulveda-Toro, M.D.

February 25, 2016